UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

IN RE: INCRETIN BASED THERAPIES PRODUCTS LIABILITY LITIGATION *This Document Relates to All Cases*	MDL Case No. 13-md-02452-AJB-MDD AMENDED JOINT SUBMISSION REGARDING PLAINTIFFS' AND DEFENDANTS' FACT SHEETS Hon. Mitchell D. Dembin

This joint motion is submitted pursuant to the Court's Order Regarding Discovery Disputes Identified in Joint Submission Filed November 18, 2013 (ECF No. 186), which was filed on November 19, 2013 (ECF No. 192).

PLAINTIFFS' POSITION:

1. **Introduction:**

Plaintiffs hereby move this Court to temporarily suspend the use of the "Long Form" Plaintiffs Fact Sheet ("PFS"), which has proven unnecessarily burdensome and costly. Plaintiffs request that the Court instead order the use of a Short Form PFS, which provides Defendants with all the information they require at this stage of the litigation, but which is less burdensome and more economical to use than the Long Form PFS. *See* Exhibit 1.

Plaintiffs further move that the Long Form PFS be used again later in this litigation, when the "Discovery Pool Cases" have been selected. Those cases will be subject to the comprehensive Bellwether Trial Plan and Case Management Scheduling Order (to be submitted by the Parties by January 11, 2014), and will be appropriate for the Long Form PFS.

Finally, Plaintiffs move the Court to adopt the attached proposed Defendants' Fact Sheet ("DFS") (*see* Exhibit 2), and to require its use in the same cases for which the Court requires the use of the Long Form PFS. The Parties will then have complete PFS and DFS information when selecting Bellwether candidates.

2. **Plaintiffs' Fact Sheets**:

A. **Procedural Background**:

This Court granted a joint motion submitted by the Parties approving the use of the "Long Form" PFS in all related cases prior to formation of this Multidistrict Litigation ("MDL"). *See Moses Scott v. Merck, et al.*, 12cv2549 (EFC No. 33). In their negotiations, the Parties agreed that the Long Form PFS process, including both Plaintiffs' completion of the Long Form PFS and Defendants' "deficiency notices and requests," would be conducted in good faith. It was also understood that the Long Form PFS would not be used to create unnecessary burdens on Plaintiffs. Although the PFS and DFS were negotiated separately, it was expected that the obligations and burdens of the PFS and DFS would be substantially similar. Thus far, that has not been the case.

Plaintiffs have completed dozens of Long Form PFSs since the use of the Long Form PFS was approved. Through experience, they are now fully aware of the burdens created by both the Long Form PFS and Defendants' insistence on issuing "deficiency notices and requests." In short, Plaintiffs estimate that it takes approximately six or more hours of staff time to complete a Long Form PFS – and that does *not* include the time the client spends, *or* the significant additional time and resources spent responding to Defendants' "deficiency notices and requests."

After the first MDL Status Conference, held on October 17, 2013, the Court issued its Order Following Status Conference Filed October 18, 2013 (ECF No. 143). In that Order, the Court noted:

> The filing pace is dictated by Plaintiffs' obligations to provide "Plaintiff Fact Sheets" and authorizations as agreed to by the Parties. The Parties may consider a less exhaustive preliminary "Plaintiff Fact Sheet" to facilitate quicker filing. This would be without prejudice to the prior more detailed fact sheet.

This is significant both because it shows the Court may welcome the use of a Short Form PFS, and because it shows the Parties have known for some time that a Short

Form PFS may come into play to aid the orderly progress of this litigation.

B. **The PFS and DFS in *In Re: American Medical Systems, Inc., Pelvic Repair Systems Products Liability Litigation*, MDL No.2325**:

Plaintiffs ask that the Court consider and adopt the approach taken in *In Re: American Medical Systems, Inc., Pelvic Repair Systems Products Liability Litigation*, MDL No. 2325, presided over by Chief Judge Joseph R. Goodwin. In that litigation, the Parties agreed to – and the Court ordered – a Short Form PFS to be used by all Plaintiffs until the entry of an Order identifying the "Discovery Pool Cases." *See* Exhibit 3. After identification of the Discovery Pool Cases, Plaintiffs had 60 days to submit a Long Form, or "full" PFS for each such case. *Id.* At that time, defendant American Medical Systems, Inc. ("AMS") was also required to complete a DFS for each of the Discovery Pool Cases. *Id.* This approach saves the time and resources required to complete Long Form PFSs and DFSs for each case, and is fully consistent with the procedures outlined in the Manual for Complex Litigation, Fourth (*see, e.g.*, Section 22.8: "Other steps to organize discovery and divide work into manageable categories include organizing discovery in waves[.]").

C. **Plaintiffs' Proposed Short Form PFS and Implementing Order**:

Plaintiffs' proposed Short Form PFS contains a wealth of information that will enable both Parties to identify the potential Discovery Pool cases. In particular, the Short Form PFS includes complete information about the prescribing physician, which Defendants' products were used, the dates of use, the dose consumed and the course of administration. *See* Exhibit 1. It also contains detailed information about the Plaintiff's diagnosis, the date of diagnosis, the diagnosing physician, the types of treatment, the dates of treatment, the location of treatment, and complete information about the treating physician and facility, as well as Plaintiff's pharmacy. *Id.* It also requires each Plaintiff to provide copies of key documents currently in their possession or that of their counsel, including death certificates, estate documents, diagnostic imaging, consent forms signed during

treatment, literature and warnings regarding Defendants' products, medical records, pharmacy records and autopsy reports. *Id*.

Finally, the Short Form PFS contains a Medical Authorization that allows Defendants to order the medical and pharmacy records identified in the PFS. *See* Exhibit 4. Defendants will receive relevant and highly detailed information for each case filed, whether or not that case is selected for the Discovery Pool.

D. **Defendants' Deficiency Notices and Requests**:

The current Long Form PFS, as discussed above, has proven onerous and costly to complete. When coupled with Defendants' multiple "deficiency notices and requests," the Long Form PFS creates an even bigger – and unnecessary – drain on the Parties' resources. The Long Form PFS has significant potential for abuse.

For example, in "deficiency" letters dated October 17 and 21, 2013, one Defendant asked for eye care records in one letter and the records of 17 additional facilities (including insurance records) in the other letter, all without any reference to *why* Defendant believed the additional records were necessary or even relevant. A meet and confer session was held on October 24, 2013. Plaintiffs' Counsel noted that Defendant appeared to be simply reviewing each set of medical records; identifying any other providers mentioned in the records; and ordering the other records without regard to whether they were needed or relevant.[1]

Plaintiffs are concerned that this cycle will be repeated again and again until no more providers or insurers can be identified. This costs much and gains little. In fact, all it "gains" is that Defendants would end up with a *full set of medical and insurance records*, unrestricted by relevance or date, for *each* Plaintiff, whether or not that that Plaintiff was ultimately included in the Discovery Pool.

[1] The exhibits establishing the facts referred to in this section have been omitted due to HIPAA privacy concerns. If Defendants dispute the underlying facts, Plaintiffs will submit redacted copies of the relevant documents.

E. **A Two-Tiered Approach to Fact Sheets is Not Prejudicial**:

One of Defendants' arguments throughout these negotiations has been that they would somehow be prejudiced by the use of a Short Form PFS. That is not true. The Parties have already been ordered to submit a comprehensive Bellwether Trial Plan and Case Management Scheduling Order by January 11, 2014. The plan will necessarily address selecting potential cases for the Discovery Pool. Here, as in *In Re: American Medical Systems, Inc., Pelvic Repair Systems Products Liability Litigation*, MDL No. 2325, the Court can order a Short Form PFS to be used by all Plaintiffs until an Order is entered identifying the "Discovery Pool Cases." Once those cases are identified, Plaintiffs can be required to submit a Long Form PFS for each Discovery Pool case within 60 days (or similar timeframe). In the meantime, the Defendants will have received all the information they need (not all they are *asking* for, or *want*, but what they *need*) to select cases for the Discovery Pool, but neither side will have wasted its resources engaging in essentially full written discovery on the great many cases that will never reach the Discovery Pool.

F. **Completing a Long Form PFS on Every Case will "Waste" Defendant Amylin's Available Insurance Proceeds:**

The continued use of the Long Form PFS will result in an unnecessary and inappropriate "wasting" of what may be very limited assets of Defendant Amylin. The Court will be asked to resolve a dispute over disclosures by Defendant Amylin regarding its insurance coverage pursuant to this Court's Order Regarding Discovery Disputes Identified in Joint Submission Filed November 18, 2013 (ECF No. 186), filed on November 19, 2013 (ECF No. 192). At the core of this dispute is Plaintiffs' concern that Amylin may be grossly underinsured if found liable in this MDL. Plaintiffs are also concerned that Amylin may have "wasting" insurance policies, such that the costs of defense act to reduce the available policy limits. The use of the Long Form PFS significantly increases the costs for the Defendants, including Amylin, since it sets forth an expansive range of Plaintiffs' records to

purchase, organize and store. The Long Form PFS has also prompted numerous "deficiency" letters, the preparation and resolution of which *adds* significantly to the costs of defense and therefore *subtracts* significantly from the available insurance coverage on a "wasting" policy. This waste can easily be ameliorated by the use of a Short Form PFS until Discovery Pool Cases have been selected.

The substance of Defendants' response to this point has been that Amylin is free to conduct its defense in any way it deems fit, including defending in ways that unnecessarily deplete insurance proceeds that would otherwise be available to successful plaintiffs in this MDL. Plaintiffs respectfully disagree, and therefore seek the Court's assistance to prevent such waste.

3. Defendants' Fact Sheet:

A. **Procedural Background:**

As discussed above, the Defendants' Fact Sheet was negotiated separately from the Plaintiffs' Fact Sheet. Plaintiffs expected that the obligations and burdens of the DFS and PFS would be substantially similar when both were completed. However, Defendants are now trying to minimize their obligations and burdens relative to those of Plaintiffs. The main areas of disagreement with respect to the DFS are set forth below, and are highlighted in Exhibit 2.

B. **Department and Custodial Files and Sales Representative Searches:**

Defendants seek to limit their obligations by searching only databases when responding to the DFS. More specifically, they want to avoid looking for relevant, responsive information from other common sources, such as department and custodial files and sales representatives. That is not acceptable. Defendants are fully aware that people – not databases – visited Plaintiffs' prescribing doctors to sell their drugs. Department and custodial files and sales representatives are necessary to obtain complete and meaningful responses for the DFS.

The gist of Defendants' argument for limiting their searches to databases has been that doing more would be unduly burdensome. Plaintiffs have three responses

to that. First, Plaintiffs' proposed DFS is already remarkably *un*-burdensome for the defense simply because it applies only to the limited subset of cases chosen for the Discovery Pool. Even a *less* informative DFS would entail considerably *more* "burden" on the defense if – as is often the case in MDL drug litigation – a DFS were required for every case filed in the MDL. Second, the right to sell their products in the U.S. market has allowed Defendants to profit enormously. It is fundamental that with rights come responsibilities. "Part of the cost of doing business in the United States is the responsibility to respond to the orderly demands of litigation[.]" *New Medium Technologies LLC v. Barco N.V.*, 242 F.R.D. 460, 469 (N.D. Ill. 2007). Third, it is beyond dispute that the Defendants in this case are corporate giants.[2] The notion that they will find it "unduly burdensome" to perform the requested searches on the relatively small number of Discovery Pool Cases is fanciful. Defendants should be required to perform these basic searches.

Complete and accurate information is equally important to *both* sides when selecting cases for Bellwether trials. Plaintiffs are simply asking Defendants to do what Plaintiffs agreed to do from the outset: conduct thorough and complete searches for relevant and responsive information when completing Fact Sheets.

C. **Relevant Time Period:**

Defendants want the time period to run from the date the Defendant's medication was launched until 30 days after Plaintiff's last prescription period, as identified by Plaintiff's pharmacy records. To ensure that no relevant information is omitted at the front end, Plaintiffs request that the time period start from the date of FDA approval of the medication. Plaintiffs also request that the time period end with the due date for the Plaintiff's PFS, since this should capture both the use of any samples consumed after prescriptions ended, and any follow-up questions and

[2] *E.g.*, Yahoo Finance showed market capitalizations of $141.36 billion for Merck; $93.91 billion for Novo Nordisk; and $53.35 billion for Eli Lilly on December 14, 2013. No figure was available for Amylin, now owned by Bristol-Myers.

related dialog Plaintiff's prescribing physician may have had with a Defendant after the Plaintiff stopped using the Defendant's medication.

D. **Documentation Relating to Benefits, Risks, Safety and/or Use of Defendants' Products Given to Plaintiffs' Treating Physicians:**

Plaintiffs' proposed DFS contains the following question:

> Have you ever provided to the Prescribing Healthcare provider(s) documentation related to the benefits, risks, safety and/or use (i.e. published studies, clinical trial data, journal articles, etc.) of the Medication? __Yes __No
>
> If yes, please state and/or produce:
>
> 1. The type of documents provided;
> 2. The date the documentation was delivered;
> 3. The method the document was delivered;
> 4. A copy of the document delivered.

See Exhibit 2, § IV(B). Defendants refuse to provide this information unless they are allowed to limit their searches to databases only. However, this is a "classic" pharmaceutical mass tort MDL in which every Complaint the PSC is aware of includes a failure to warn count. The "Learned Intermediary" defense has been pleaded in every Answer. Documentation provided to the Plaintiff's prescriber about the benefits and risks of the medication goes directly to the heart of the warning claims and defenses. Database-only searches will inevitably side-step crucial information available from the files of those who communicated directly with the doctors. This information is required by Plaintiffs' counsel as they analyze these cases and prepare to select potential Bellwether trial candidates.

E. **Plaintiff-Specific Advertising Data:**

Plaintiffs' proposed DFS also contains the following question:

> Aside from national advertising (i.e. advertising that was not directed to any specific geographic region), did you advertise Defendant's medications in the Media Market in which Plaintiff lived at the time that he or she used Defendant's Medication as disclosed in the PFS? __Yes __No

See Exhibit 2, § V. If a Defendant answers affirmatively, then the proposed DFS

asks for more specific information about its advertising, limited to the region where Plaintiff lived when using the Defendant's medication, and the region where Plaintiff's prescribing provider was located during that time. Defendants have refused to provide this information. Again, this is a classic pharmaceutical MDL. Plaintiffs are entitled to the requested information because they need to know how the benefits, risks, safety and/or proper use of the medication were presented to the Plaintiff and the prescribing provider. Such information is required as Plaintiffs prepare for the selection of potential Bellwether cases.

F. **Defendants' Knowledge of a Plaintiff's Medical Condition:**

Plaintiffs' proposed DFS also contains the following question:

> Other than as may have occurred in connection with any adverse event report or this lawsuit, have you contacted and/or been contacted by Plaintiff, Plaintiff's physicians, nurses, physician assistants, or anyone else expressly on behalf of Plaintiff and/or expressly concerning Plaintiff regarding your Medication and/or Plaintiff's medical condition? __Yes __No
>
> If your answer is "yes," please state:
>
> 1. The name of the person(s) who contacted you;
> 2. The person(s) who you contacted;
> 3. Describe the general substance of any such contacts; and,
> 4. Produce any documents exchanged or created related to such contacts.

See Exhibit 2, § VI(A). Defendants again say they will not answer certain questions (Nos. 3 and 4) unless they are allowed to limit their searches to databases only. However, what the Defendants know about a Plaintiff's medical condition is classically the type of relevant information disclosed in every pharmaceutical mass tort case. That information will not always be found in a database, but it is a prerequisite to making informed decisions on potential Bellwethers.

G. **Documents:**

Plaintiffs have requested – and Defendants have refused to provide – the following documents listed in Section VII of the proposed DFS (*see* Exhibit 2):

6. Any and all documents that relate or refer to Plaintiff in your possession, other than pleadings and documents received from Plaintiff.
7. Any and all documents sent to or received from any of Plaintiff's Healthcare Providers, including cover pages.
8. Any and all other documents that reflect any communication with Plaintiff's Healthcare providers regarding your product.
9. Any and all Adverse Event Reports for Plaintiff and all back-up data, including but not limited to any and all correspondence to/from the FDA regarding said AER and/or said Plaintiff.
10. Aside from national advertising, copies of any and all advertisements directed toward the media markets in which the Plaintiff resided and/or Plaintiff's Treating Healthcare Provider's office is located, as identified in Section IV. A, B or C.
11. Any other document printout, communication, or tangible items identified in, referred to, and/or pertaining to any of the requests or responses in Section I-V.

Once again, the above requests ask for nothing more than would be expected in every pharmaceutical mass tort case. The information should be provided because it is necessary for Plaintiffs to properly select Bellwether candidates.

H. **Timing of the Defendants' Fact Sheet:**

Plaintiffs know that sauce for the goose is sauce for the gander. It is costly to complete a PFS, and the same is true for a DFS. Plaintiffs have offered Defendants a valuable *quid pro quo*: if Plaintiffs can limit the Long Form PFS to the Discovery Pool, then Defendants can do the same with the DFS. However, each DFS provides useful information, and Plaintiffs would much prefer to have one for every file. If Plaintiffs must continue to use the Long Form PFS in every case, they respectfully request that the Parties be put on equal footing by also requiring Defendants to submit a DFS – using more than database-only searches – for every case.

DEFENDANTS' POSITION:

1. PLAINTIFF FACT SHEETS

A) Background

Over seven months ago, the Parties negotiated and this Court entered a Plaintiff Fact Sheet ("PFS") in the SDCA coordinated proceeding. See May 3, 2013, ECF No. 31 ("Joint PFS Submission"). The same lead Plaintiffs' counsel involved here joined in those negotiations. They never suggested that the end product might be a "Long Form" PFS. It always was understood to be the only PFS, intended to obviate the need for protracted written discovery directed to each Plaintiff and ensure that Defendants have sufficient information to evaluate the cases for the bellwether process, early on and while the Plaintiffs are still available. The need to collect this information early is particularly acute here, given the terminal disease at issue.

Plaintiffs no longer want to complete the PFS they negotiated, claiming it is too burdensome. But most, if not all, of this information should have been gathered by Plaintiffs' counsel before filing the cases. Moreover, having placed their health condition at issue, Plaintiffs should not be resistant to Defendants gathering their medical records at Defendants' cost, not Plaintiffs'.

For the first time, Plaintiffs propose a substantially truncated PFS in exchange for eliminating the Defendants' Fact Sheet ("DFS") obligations entirely until a discovery pool is selected. *See* Exhibit 5. Defendants cannot agree to this proposal because (1) the receipt of anything less than a full and complete PFS at the outset is prejudicial to Defendants; and (2) unlike the DFS, the PFS is Plaintiffs' sole early written discovery obligation—Plaintiffs already have served Defendants with extensive document production requests and interrogatories and Defendants already have started general company document production.

Discovery is not a strict "tit for tat," and even without a DFS, the Defendants' burdens dramatically outweigh the Plaintiffs' obligations. Indeed, if

precise proportionality were the standard, the Defendants would be done—many times over—with their discovery obligations to these Plaintiffs.

(1) PFS Currently In Use

The PFS has only 11 pages, along with one page of document requests.[3] The requests seek critical yet basic information from each plaintiff, including medical background, treating healthcare providers, and personal demographic information on top of information about use of the drugs at issue and pancreatic cancer diagnosis. Plaintiffs have used this PFS since the commencement of the MDL without objection. In fact, Defendants already have received completed forms from "dozens" of plaintiffs[4], most of them represented by members of the PSC. Until recently, the only disputes Plaintiffs raised with Defendants were over the scope of Defendants' deficiency letters and medical record authorization requests.[5] Only as the Parties reached an impasse in negotiating a DFS, did Plaintiffs demand the use of a truncated PFS.

(2) Plaintiffs' Proposed Truncated PFS

Plaintiffs suggest that the truncated PFS includes all the information Defendants would need to evaluate a case for trial selection, which in their view is limited to information regarding the product(s) at issue and a pancreatic cancer diagnosis. Without established bellwether selection criteria, Plaintiffs' assumptions of what may be relevant to Defendants' case assessment are baseless. Their proposed PFS would deny Defendants the most basic information about the type of treatment Plaintiff is receiving for cancer or other claimed injury, all the specific

[3] Compare to PFS' entered in similar MDL litigations: Chantix (MDL No. 2092) **22 pages**; Bextra & Celebrex (MDL No. 1699) **16 pages**; Diet Drugs (MDL No. 1203) **21 pages**; Gadolinium Contrast Dyes (MDL No. 1909) **23 pages**.

[4] As cited by Plaintiffs in Section 2.A. of this submission.

[5] Defendants offered a compromise position. Defendants would agree to limit deficiencies to sections of the PFS left entirely blank, and cite the location of the medical record referencing the healthcare provider whose authorization is sought. Plaintiffs rejected this proposal.

injuries alleged to give rise to compensable damages (information also not provided in the Master Short Form Complaint), and the names of any healthcare providers who did not treat the plaintiff for cancer or other claimed injury, or prescribe the drug at issue. It seeks to remove information regarding prior medical history, including diabetes diagnosis and treatment, co-morbidities, risk factors for pancreatic cancer and other significant medical conditions—information essential to medical causation, warning causation, and damages. Plaintiffs omit questions regarding family members, family medical history, including relatives' cancers, plus the Plaintiffs' education, prior residences, marital status, disability status, employment history, lost earnings, medical expenses, and known or potential fact witnesses in their case.

What remains is a three-page "bare bones" form requiring Plaintiff only to provide information on incretin drug use, the pharmacy where the drug(s) at issue was filled, prescribing physician(s), alleged injury and diagnosing physician. Plaintiffs cite to one MDL using a truncated PFS, but fail to mention that the injuries alleged in the pelvic mesh medical device MDL are not aggressive cancers. There, early and more detailed background is not essential.

(3) Defendants Already Made Concessions To Arrive At The Current PFS Form

The Parties extensively negotiated the PFS prior to this Court implementing it approximately six months ago. Defendants already conceded many points to arrive at the version used today. Plaintiffs now wish to set a new floor with the previously-negotiated version to start negotiations once again. It is unfair for Plaintiffs to return with a new proposal for the Court to consider.

B) Plaintiffs' Proposed Truncated PFS Would Be Prejudicial

(1) Critical Medical History May Be Lost Forever

The condition at issue in the litigation—pancreatic cancer—has a shortened life expectancy. Consequently, the Parties are faced with the unfortunate fact, as

alleged by Plaintiffs' counsel, that many Plaintiffs may have little time left. In order to properly evaluate and defend these cases, it is vital that Plaintiffs supply the detailed information requested in the PFS while they are available to respond on their own behalf about their allegations, injuries, history, and treatment. The Defendants would suffer significant prejudice unless the full PFS as already entered is completed timely by each Plaintiff and would have no choice but to seek the other necessary information by individual interrogatories or other discovery methods.

(2) The Truncated PFS Would Put The Parties On Unequal Footing

The Plaintiffs' past and current health are central issues in this litigation. Defendants must evaluate all of Plaintiffs' existing medical conditions and medical treatment histories to identify injuries, determine causation and evaluate damages. Contrary to Plaintiffs' arguments, without a "complete" picture of a Plaintiff's medical condition and history, Defendants would be at a marked disadvantage in trying to distinguish among cases for bellwether trial selection. The proposed truncated PFS would offer only minimal information—proof of use of Defendants' medications and diagnosis of pancreatic cancer. The cases would otherwise have little or no distinction to Defendants, putting them at a significant disadvantage without further information when picking discovery pool or bellwether cases.

The truncated PFS does not provide information that is common, reasonable and appropriate to consider in assessing potentially suitable trial cases. Plaintiffs would be the sole party in possession of crucial facts regarding Plaintiffs' medical conditions and histories. In other words, Plaintiffs seek to deny Defendants' ability to make such an assessment fairly and on equal footing.

C) The PFS Is Plaintiffs' Sole Early Discovery Obligation

Plaintiffs argue that completing the PFS is burdensome because allegedly it takes several hours to complete. While Defendants disagree that the PFS is

burdensome, Plaintiffs omit that this 11-page form is their *only* early discovery obligation. The PFS was negotiated to take the place of pre-discovery pool written discovery obligations for Plaintiffs (which is why it is comprehensive and includes document requests for medical records). Contrasting Plaintiffs' "six hours" with the obligations Plaintiffs impose upon Defendants—significant time and money devoted to answering extensive written discovery, completing large document productions, and preparing numerous company witnesses for deposition on top of the DFS obligations—Plaintiffs' burdens are minimal.

Plaintiffs filed these lawsuits, putting their health at issue, and have an obligation to disclose to Defendants basic information that would allow Defendants properly to evaluate and defend these cases in a timely manner. Such is the point behind written discovery under the Federal Rules. The Court should order the implementation of the PFS already used in these cases and entered in the *Scott* case.[6] Eliminating the only early source of information that Defendants have about Plaintiffs would force Defendants to issue traditional written F.R.C.P. discovery requests in every filed case to put the Parties on equal footing in terms of Plaintiffs' case. In the last MDL hearing when discussing Plaintiffs' PFS obligations, Judge Battaglia stated: "But if we don't get most of this information before the defense, we restrict our ability, ultimately, to adjudicate the case. And I would hate to resort to individual document requests, a flurry of individualized subpoenas and so forth."

[6] Plaintiffs allege that PFS obligations will "waste" limited insurance proceeds of defendant Amylin. Plaintiffs cite nothing for their suggestion that Amylin's liability insurance gives them a right to dictate Amylin's defense strategy, and Amylin objects to Plaintiffs claiming a seat at the defense counsel table. While Amylin will address Plaintiffs' insurance-related arguments in the separate brief, it bears noting that Plaintiffs are unconcerned with depleting Amylin's insurance coverage on such things as re-producing millions of pages of documents that Plaintiffs already have. At any rate, Plaintiffs argument ignores that all four Defendants are entitled to discovery from each and every Plaintiff.

Nov. 21, 2013 Tr. of MDL Hr'g. at 15:6-10. The PFS form agreed to by the Parties was intended to take the place of those procedures.

2. Defense Fact Sheets

A) Background

The fundamental and overriding misconception fostered by Plaintiffs with respect to the DFS is that Defendants are trying to minimize their obligations relative to Plaintiffs'. Plaintiffs' Position creates the misimpression that the PFS and DFS are "tit-for-tat," and that the relative discovery burdens borne by the Parties under each should therefore be equal.

The PFS, however, is the primary, and often *only* written discovery request to which a plaintiff responds. Defendants, on the other hand, have to undertake significant discovery efforts, both case-specific and generic, including responding to extensive interrogatories, requests for production and admissions, reviewing and producing large numbers documents, and preparing and producing numerous company witnesses for deposition in addition to the DFS commitments. As part of Defendants' overall discovery obligations, the DFS is intended to make available reasonable case-specific discovery at an early litigation stage, namely information Defendants may have that is relevant to the *particular* Plaintiff and his/her prescribing healthcare provider. Plaintiffs call for unreasonable, burdensome searches by Defendants at any early stage of this MDL for information concerning a particular Plaintiff and the prescribing physician(s) through the documents of individual sales representatives who communicated with those physicians.

Moreover, unlike the PFS, the Court has not yet entered an Order pertaining to the DFS. Therefore, Defendants are not asking for reconsideration of a previously negotiated order. Nor was there any suggestion during the PFS negotiations a year ago that the DFS might have equivalent discovery obligations. The PFS and DFS are separate and distinct discovery tools, with different objectives for either side. The Plaintiffs will have in their possession most of the

information the Parties need to distinguish among Plaintiffs in bellwether selection and the PFS should reflect that information. Defendants respectfully ask the Court to implement Defendants' version of the DFS.

B) Timing Of The DFS

The Parties never discussed the timing of the DFS. That Plaintiffs are willing to defer the DFS shows they do not believe it is critical to the discovery pool selection process. Furthermore, the Parties did not contemplate a PFS and DFS "exchange." While Defendants must use the information in the PFS in order to complete a DFS, the PFS does not need to serve as a trigger for the DFS deadline. Therefore, the DFS should be required to be produced only in cases selected for the discovery pool and/or bellwether trials, once a bellwether plan is adopted by the Court, and only in cases with a full and non-deficient PFS.

Should the Court decide to order Defendants to produce a DFS for all cases prior to the discovery pool, responsive information in the DFS should be limited to database searches only. Defendants do not oppose responding to broader case-specific requests beyond database searches at a later, more appropriate time for the cases in the discovery pool.

C) Disputed Issues

Four disputes exist that the Court must address with respect to the substance of the DFS.

(1) <u>Responsive Information Can And Should Be Produced From Reasonably Accessible Electronic Databases Only</u>.

Plaintiffs argue that Defendants' DFS discovery obligations should mirror Plaintiffs' PFS obligations. Plaintiffs claim that because they have to interview their clients and review medical records to complete the PFS, Defendants should have to interview company witnesses and review custodial files to complete the DFS. Plaintiffs miss the point entirely. Plaintiffs' early discovery obligations are reduced to the responses they provide in the PFS. To reach agreement on the PFS,

Defendants' substantially limited their right to seek additional written discovery from the Plaintiffs, a point embodied in the Court's Order implementing the PFS.

Plaintiffs, on the other hand, are not limited by the DFS. Quite the contrary, as explained, the DFS is but a corollary to the significant and expansive discovery obligations that Defendants are called upon to meet by Plaintiffs, and which has no analogue on the other side. Defendants not only have to complete the DFS but must undergo substantial generic and case-specific discovery. The PFS/DFS obligations were never intended to be on equal footing with each other. Defendants' overall discovery obligations far outweigh Plaintiffs' obligations.

As always, Defendants' obligation to produce information in response to the DFS should be based on what would constitute a reasonable search for information. At any stage prior to discovery pool selection, a search for information on a case-by-case, Plaintiff-by-Plaintiff, and prescriber-by-prescriber basis should be based on centralized, officially stored, and reasonably accessible information maintained in databases in the ordinary course of business. The nature of the information called for by the DFS should not be—for all plaintiffs at this stage of the litigation—done on a custodial file basis. For example, embracing Plaintiffs' approach would require Defendants to review custodial files, which can be tens of thousands of pages, for sales representatives identified for each case (who will differ for each case based on dates of employment and geographic area).

Defendants' databases contain the official memorialization of the information Plaintiffs are requesting. For example, databases where Defendants track and store records of contacts the sales representatives made to prescribing physicians (commonly referred to as the "call note database") are reliable sources of information and contain a full or nearly-full response to areas the DFS covers. Custodial files, on the other hand, are second-hand sources in which some information may exist, but are not official sources from the company, nor are they guaranteed to contain the information Plaintiffs are requesting.

To require Defendants at this stage to search for marginally responsive information outside of reasonably accessible databases is unduly burdensome and is not justified by a countervailing need for the information now. To burden Defendants with an entirely additional series of witness interviews, document collections and reviews in every filed case, all within the short time frame Plaintiffs request production of a DFS, is unreasonable. Case-specific discovery will be conducted for cases subject to a trial date at the appropriate time in the scheduling order, and may include review of the relevant sales representatives' files for a trial case. Plaintiffs' position that Defendants should be required to undergo all of that discovery in the DFS now before the discovery pool and bellwether cases are even picked, is unreasonable. For DFS purposes, the review and production should be limited to information contained in reasonably accessible databases.[7]

(2) The Relevant Time Frame For Responsive Documents Is From Date Of Product Launch Through End Date Of Prescription Period.

Another disputed issue is what time period generally should govern the production of responsive information. Defendants' position is that responsive information in the DFS should be produced *from* the date of each Defendant's product launch, *to* the end date of Plaintiff's prescription period for each product ingested, as determined from the Plaintiff's prescription records.

In this brief, Plaintiffs expand their request for the first time and are now proposing a different relevant time period never before negotiated—i.e., date of

[7] To the extent Defendants' obligation to produce responsive information is limited to a reasonable search of database information, Defendants do not object to requested information in the DFS relating to (1) benefits, risks and safety and/or use of Defendants' products given to Plaintiff's prescribing physicians; and (2) Defendants' knowledge of a Plaintiff's medical condition. Defendants have never refused to provide this information. Plaintiffs' arguments to the contrary in Sections 3.D and F are inaccurate. These issues are merely part of the scope of dispute over what search is reasonable.

FDA approval[8] through present. During negotiations, Plaintiffs agreed to a start date from the time of product launch and offered an end date of 120 days after use. The disputed issue was how to determine "use," with Defendants suggesting that it is best determined based on the prescription records produced with the PFS.

Defendants are entitled to a cutoff date that has a date certain. A cutoff date of "the present" requires Defendants to engage in unending supplementations of each DFS well after the Plaintiffs stopped taking the drug and potentially even after the death of the product user. In addition, most of the requested information in the DFS pertains to the particular Plaintiff's prescribing physician at the time they would have been making the prescribing decision. Requiring the production of information that post-dates a Plaintiff's last prescription period is not relevant.

(3) Advertising Data Is Not Appropriate With The DFS.

Plaintiffs request documents and information on local advertising and marketing in the geographic areas of Plaintiffs' prescribing physicians. Discovery as to Defendants' advertising activity is conducted most efficiently through generic discovery, not on a Plaintiff-by-Plaintiff basis in the DFS. The information Plaintiffs seek is maintained in departmental files and custodial files, and should be subject to production under the general ESI protocol. Furthermore, Plaintiffs' proposed DFS requires Defendants to make a case-by-case determination as to what potential "Media Market" the prescribing physician is located within. Plaintiffs fail to define "Media Market" with any objective criteria, despite requests from Defendants, and leave Defendants unable to search for this data even if it was readily available, which it is not. To conduct searches for this information for each DFS at this stage is unduly burdensome.

[8] Any relevant time period should start with the day each drug was available for sale on the market, whether or not that coincides with the FDA approval date. Any other time period would engage Defendants in needless, irrelevant discovery.

(4) Plaintiffs' Document Requests Are Extremely Broad And Outside The Scope Of The DFS.

Plaintiffs include six document requests not appropriate for the DFS. To comply with the additional document requests Plaintiffs propose—several of which do not relate to the products or Plaintiffs at issue—would require Defendants to interview witnesses and review documents. Plaintiffs have not provided any reason as to why they need these documents for every DFS.

3. CONCLUSION

For the foregoing reasons, Defendants respectfully request that this Court (1) order utilization of the full PFS form entered in the *Scott* case for the entire MDL docket at the outset of the case, attached as Exhibit 6; (2) deny use of a truncated PFS; and (3) implement of Defendants' version of the DFS for use at the discovery pool/bellwether stage.

The Defendants request oral argument. Because these issues are so pervasive to the docket, the Defendants believe it is important to have the opportunity to clarify any issues for the Court through oral argument, either via telephone or in-person.

JOINT STATEMENT:

Once the Court rules on these discovery disputes, the Parties believe they can meet and confer and jointly propose a corresponding Implementing Order for each Fact Sheet (or competing orders) within seven (7) days of the date of the Court's order.

Dated: December 19, 2013

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Dated: December 19, 2013

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SIGNATURE ATTESTATION

I hereby certify that authorization for the filing of this document has been obtained from each of the other signatories shown above and that all signatories concur in the filing's content.

Dated: December 19, 2013

/s/ Michael K. Johnson
Michael K. Johnson

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

IN RE: INCRETIN BASED THERAPIES PRODUCTS LIABILITY LITIGATION	MDL Case No. 13-md-02452-AJB-MDD
This Document Relates to All Cases	**CERTIFICATE OF SERVICE**

I, the undersigned, declare as follows:

I hereby certify that on December 19, 2013, I electronically filed the foregoing with the clerk of the court using the CM/ECF system which will send notification of such filing to the e-mail address denoted on the electronic Mail Notice List.

I certify under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on December 19, 2013, at Minneapolis, Minnesota.

/s/ Michael K. Johnson
Michael K. Johnson